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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/860,231 07/25/97 THOREL

J WPB-39818

EXAMINER

HM12/0706

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WITZ, J

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

07/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.

08/860,231

Applicant(s)

Thorel et al.

Examiner

J an C. Witz

Group Art Unit

1651



☒ Responsive to communication(s) filed on Apr 12, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 40, 41, 65, 66, 70-95, and 112-129 is/are pending in the applicat

Of the above, claim(s) 77 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 40, 41, 65, 66, 70-76, 78-95, and 112-129 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is. ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed April 12, 2000 have been fully considered but they are not persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 112***

2. Claims 40-41, 65-66, 70-76, 78-95 and 112-129 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim language drawn to "contacting only an area of human skin whose integrity has not been breached by injury" or "contacting only an area of human skin whose integrity has not been breached by a wound" does not find support in the specification as originally filed and is therefore considered new matter.

Applicants assert that because they disclose in the specification teaches that the composition may be applied to skin for both cosmetic and medicinal purposes, the embodiment of skin "whose integrity has not been breached by injury" or "whose integrity has not been breached by a wound" is clearly envisioned within the scope of the original disclosure. This argument has not been found to be persuasive because the scope and definition of this embodiment cannot be determined from the original disclosure as filed. There are no definitions of the terms "injured" or

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“breached by a wound” to be found in the specification. It is not clear as to what is included in the claim and what is not. For example, Applicants assert that what they refer to as “weakened skin” and “older skin” falls within the definition of skin “whose integrity has not been breached by injury” or “whose integrity has not been breached by a wound”; Applicants appear to be arguing that if the extreme outer surface of the epidermis does not have a visible open defect, then the integrity of the skin has not been breached. However, when the terms “weakened skin” and “older skin” are given their broadest reasonable interpretation, they include skin “injured” by exposure to sun, wind and other elements. Applicants repeatedly use the term “skin” in the specification. The term “skin” refers to the integument, composed of both the dermis and the epidermis. The epidermis is composed of multiple distinct layers containing a total of upwards of 50-60 layers of epithelial cells. Below the epidermis lies the dermis, a layer of connective tissue containing nerves, hair follicles, blood vessels and glands. Injuries can occur that “breach the integrity” of these areas without causing a visible open defect in the top of the integument; are these included or excluded? The specification fails to address this issue. Finally, The epidermis is constantly replenishing itself. The top layers of the integument are actually dead cells and continually slough off merely due to contact with surfaces such as clothing, towels, bedsheets and other surfaces. The entire integument is replaced 35-45 days. Due to the multiple cells layers that make up the integument and their microscopic nature, actual breaches of the top layers of the integument can occur; however, they are not visible to the unaided eye. Again, it is not clear that this situation is either included or excluded from the claimed subject matter. Due to the

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lack of disclosure as filed, it simply cannot be determined what is comprised by the claimed embodiment and therefore the invention as claimed fails to find support in the specification.

3. Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the complex nutrient medium constitutes an exipient that potentiates an active principal. The specification fails to identify any any active principals which are potentiated by the complex nutrient medium. Therefore, the metes and bounds of the claim are not clear as to what is comprised by the term “active principal” or the term “potentiates”. The amendment fails to clarify the issue and Applicants’ assertions that one of skill “is well aware of active principals that can be added to cosmetic compositions” and “of how to use a complex nutrient medium of the present invention to potentiate such active principals” are not supported by any evidence of record.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 40-41, 65-66, 70-76, 78-95 and 112-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of the Lindenbaum patents (5,461,030 or 5,591,709) in view of the Wille, Jr. patents and further in view of Cuca.

Applicants' attempts to differentiate the disclosure of Lindenbaum from their own is simply not persuasive. Lindenbaum clearly teaches the nutrient medium as set forth in the claims. Lindenbaum also discloses that the components of the medium are conventionally used to culture keratinocytes in vitro. Further, Lindenbaum discloses that the nutrient medium has a beneficial effect not only on wounded skin, but also on normal skin that surrounds the wounds. Finally, Applicants' emphasis on the "cosmetic" applications of the claimed method are not persuasive as the scope of cosmetics and pharmaceuticals in the art at the time of the invention were co-extensive as compositions which treat conditions of the skin, to include wrinkles and aging, have

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both a pharmaceutical and a cosmetic effect. Due to the nature of the skin, any treatment that promotes the health of the skin is deemed to have a beneficial cosmetic effect. As stated previously, the entire function of the inclusion of the nutrient medium is “to provide nutrients to normal, distressed and injured cells and skin . . . .” (emphasis added) (‘790, col. 9, lines 49-54). Given the disclosure of the prior art of record, one of ordinary skill in the art would expect that “normal” human skin (assuming arguendo that such “normal” skin includes skin weakened by exposure to the elements, dehydrated skin and aging skin) would benefit from a surfeit of exogenously supplied nutrients to augment those endogenous nutrients supplied by the body. Applicants’ arguments that place continuing emphasis on the wound treatment disclosure of Lindenbaum fail to address this issue and Applicants have provided no evidence or rationale of record to support their assertions of lack of motivation. In fact, Applicants state at page 7 of the response to the previous office action that “Lindenbaum shows treating normal skin” but asserts that this treatment is limited “only for healing purposes, by stimulating cellular growth, so that new epithelial cells will colonize at the injured skin.” Since one of ordinary skill in the art would be well aware of the constant renewal and cellular growth of the epidermis and would be aware that said renewal and growth requires proper nutrients, the disclosure provides clear motivation to apply a nutrient medium to ANY skin with the reasonable expectation of maximizing the growth potential of the skin so treated.

Newly presented claim language reciting a composition “consisting essentially of water and water-soluble components” fails to provide any distinction. The transitional phrase

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“consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

For search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., PPG, 156 F.3d at 1355, 48 USPQ at 1355.

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). The components of the Lindenbaum composition are all water-soluble (including the non-steroidal anabolic hormones), and the composition may be formulated in a water-soluble excipient.

With regard to claims 117 and 121, it appears that Applicants are attempting to exclude the inclusion of the non-steroidal anabolic hormones of Lindenbaum. One of ordinary skill in the art would clearly be motivated to exclude these components since they are costly, require extended time and effort to obtain them, and if isolated from a natural source, have potential for microorganismal contamination, and would still have a reasonable expectation that the nutrient medium composition would still provide a beneficial effect to skin cells. Applicants' claims require nothing more.



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Therefore, it would have been obvious as the time the invention was made to administer a nutrient medium such as claimed (and disclosed by Lindenbaum) to “normal” skin or skin “whose integrity has not been breached by injury” or “by a wound” with the reasonable expectation of a cosmetic benefit.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

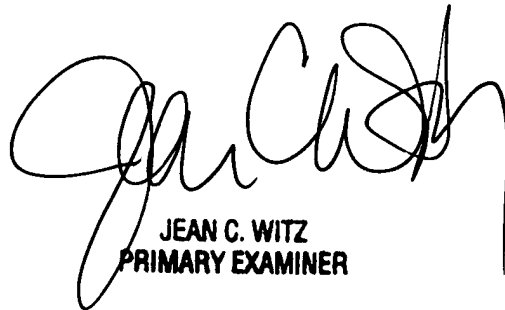
7. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073. The examiner can normally be reached on Monday through Thursday from 8:00 to 5:30. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



JEAN C. WITZ  
PRIMARY EXAMINER